

NOV 29 2001

K013264

**Appendix A (Summary of Safety And Effectiveness)**

**Submitter:**

John Gagliardi, President (**contact person**)  
MidWest Process Innovation, LLC  
7736 Woodside Court  
Maineville, OH 45039  
513-573-0085 (Telephone and fax) or  
513-573-0519 (Telephone and fax)  
JGAGL777@One.Net

**Trade Name:** Micro Stamping Corporation (MSC) Ligating Clip

**Common Name:** Ligating Clip

**Classification Name:** Implantable Clip (21 CFR, Part 878.4300)

**Summary of Safety and Effectiveness:**

The MSC Ligating Clip is substantially equivalent in function and intended use to the Edward Weck and Company Hemoclip Ligating Clip (see example of labeling in Appendix E of products presently on the market) and the Ethicon Ligacip.

**Specifically:**

the MSC Ligating Clip is exactly similar in functional design, performs the same functions and has the same intended use as these presently distributed devices mentioned above.

The packaging methods and packaging materials are exactly the same, respectively.

The MSC Ligating Clip is indicated for use as to connect internal tissues to aid in healing. This device is for prescription use only.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 29 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Micro Stamping Corporation  
MidWest Process Innovation, LLC  
C/o John Gagliardi  
President  
7736 Woodside Court  
Maineville, Ohio 45039

Re: K013264

Trade/Device Name: MSC Ligating Clip  
Regulation Number: 21 CFR 878.4300  
Regulation Name: Implantable Clip  
Regulatory Class: Class II  
Product Code: FZP  
Dated: September 25, 2001  
Received: October 1, 2001

Dear Mr. Gagliardi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and  
Neurological Devices

Office of Device Evaluation

Center for Devices and  
Radiological Health

Enclosure

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## Attachment II

### Indications for Use

Re: K013264

Device Name: MSC Ligating Clip

#### Indications for Use:

A clip like device intended to connect internal tissues to aid in healing. These clips are designed for occlusion of blood vessels and nerves, according to surgeon judgement.

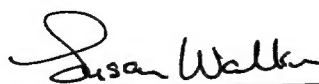
(please do not write below this line - continue on another page if needed)

Prescription Use X  
(Per 21 CFR, Part 801.109)

or

Over-the-Counter Use \_\_\_\_\_

Optional Format 1-2-96



(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K 013264